

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)	Examiner: Shaw, Amanda Marie.
)	
Joffre B. Baker, et al.)	Art Unit: 1634
)	
Application Serial No. 10/714,195)	Confirmation No: 5745
)	
Filed: November 14, 2003)	Attorney's Docket No. 39740-0005A
)	
For: GENE EXPRESSION PROFILING)	Customer No. 25213
OF EGFR POSITIVE CANCER)	
)	
)	

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF JOFFRE B. BAKER, Ph.D UNDER 37 C.F.R. § 1.132

I, Joffre B. Baker, Ph.D. declare and say as follows:

1. I am the Chief Scientific Officer at Genomic Health, Inc., Redwood City, CA 94063.
2. I joined Genomic Health, Inc. in 2000 as the Chief Scientific Officer. My scientific Curriculum Vitae, including my list of publications, is attached to and forms part of this Declaration (Exhibit A).
3. During my employment with Genomic Health, Inc., I have been involved in supervising and analyzing gene expression profiling of EGFR positive colon cancer as described in Example 2 of the above-identified patent application.
4. I am aware that some of the claims in the above captioned patent application have been rejected under 35 U.S.C. § 112 as allegedly lacking enablement. My understanding is that the rejection is based, at least partially, on the assertion that it is unpredictable as to whether the

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prognostic information obtained by the overexpression of LAMC2 and GPC3 in colon cancer cells is applicable to treatment with any EGFR inhibitor.

5. To the contrary however, it is my considered scientific opinion that Example 2 and Tables 3 and 4 are enabling and provide a strong basis for the determination that overexpression of LAMC2 and GPC3 RNA transcripts or their products in colon cancer cells is prognostic for the likelihood that a patient will or will not respond to treatment with any EGFR inhibitor.

6. In support of the conclusion made in paragraph 5 above, I offer the following evidence. As disclosed in Example 2 of the above captioned application, twenty three (23) colon adenocarcinoma patients were studied. mRNA was extracted from formalin-fixed colon tumor tissues from the patients and molecular assays of quantitative gene expression were performed by RT-PCR. After removal of the colon tumor tissue, the patients were treated with an EGFR inhibitor selected from the group, erlotinib, gefitinib, cytoximab, EMB72000, AEE788 and the patients were determined to have either a partial response, stable disease or progressive disease. The level of expression of mRNA transcripts in the colon tumors was correlated with either the partial response of the patients or the clinical benefit to the patients as described in Example 2. Table 3 of the above-captioned application shows the correlation of the gene expression with partial response of the patients. Table 4 of the above-captioned application shows the correlation of the gene expression with clinical benefit. Clinical benefit combines partial or complete response with stable disease (minimum 3 months).

7. Table 3 shows that overexpression of GPC3 in the colon tumor tissue showed a positive correlation with partial response to treatment with any of the EGFR inhibitors with a p value of 0.0097. Table 4 shows that overexpression of GPC3 in the colon tumor showed a positive correlation with clinical benefit to treatment with any of the EGFR inhibitors with a p value of 0.0025. Table 3 shows that overexpression of LAMC2 in the colon tumor tissue showed a negative correlation with partial response to treatment with any of the EGFR inhibitors with a p value of 0.0357. These results are statistically significant.

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8. It necessarily follows from paragraph 7 that the overexpression of GPC3 in colon tumor tissue positively correlates with treatment with any EGFR inhibitor and therefore overexpression of GPC3 in colon tumor tissue indicates that the patient will show an increased likelihood of response to treatment with an EGFR inhibitor. Furthermore overexpression of LAMC2 in colon tumor tissue negatively correlates with treatment with any EGFR inhibitor and therefore overexpression of LAMC2 in colon tumor tissue indicates that the patient will show an decreased likelihood of response to treatment with any EGFR inhibitor.

9. Furthermore, the results presented in Example 2 and Tables 3 and 4 were the result of treatment with a variety of different EGFR inhibitors. Therefore the prognostic information obtained by overexpression of LAMC2 or GPC3 genes is applicable to treatment with the class of drugs called EGFR inhibitors which inhibit a biological function of a native EGFR.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issued thereon.

Signed: Joffre B. Baker
Joffre B. Baker, Ph.D.

Date: Dec 21, 2006

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Principal Investigator/Program Director (Last, First, Middle):

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Joffre Baker, Ph.D		POSITION TITLE Chief Scientific Officer	
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of California, San Diego	BA	1971	Biology and Chemistry
University of Hawaii	Ph.D	1977	Biochemistry

A. Professional Experience:

1/1977 – 12/1979	Postdoctoral Fellow, Department of Medical Microbiology, University of California, Irvine
1/1977 – 12/1979	Assistant Professor, Department of Biochemistry, University of Kansas
6/1984 – 6/1988	Associate Professor, Department of Biochemistry, University of Kansas
6/1988 – 9/1990	Senior Scientist, Department of Cardiovascular Research, Genentech, Inc.,
9/1990 – 7/1991	Acting Director, Department of Cardiovascular Research, Genentech, Inc.
7/1991 – 10/1993	Director, Department of Cardiovascular Research, Genentech, Inc.
3/1993 – 2/1997	Senior Director, Research Discovery, Genentech, Inc
2/1997 - 11/2000	Vice President, Research Discovery, Genentech, Inc.
11/2000 – Present	Chief Scientific Officer, Genomic Health, Inc.

Professional Societies:

American Society for Cell Biology and American Society for Biochemistry and Molecular Biology

Awards:

7/1983 – 7/1988: NIH Research Center Development Award

B. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.

1. Baker JB, Humphreys T. Serum-stimulated release of cell contacts and the initiation of growth in contact-inhibited chick fibroblasts. Proc Natl Acad Sci U S A. 1971 Sep;68(9):2161-4. No abstract available. PMID: 4943788 [PubMed - indexed for MEDLINE]
2. Baker JB, Humphreys T. Turnover of molecules which maintain the normal surfaces of contact-inhibited cells. Science. 1972 Feb 25;175(24):905-6. No abstract available. PMID: 5008607 [PubMed - indexed for MEDLINE]
3. Baker JB, Cunningham DD. Glucocorticoid-mediated alteration in growth factor binding and action: analysis of the binding change. J Supramol Struct. 1978;9(1):69-77. PMID: 215839 [PubMed - indexed for MEDLINE]
4. Baker JB, Barsh GS, Carney DH, Cunningham DD. Dexamethasone modulates binding and action of epidermal growth factor in serum-free cell culture. Proc Natl Acad Sci U S A. 1978 Apr;75(4):1882-6. No abstract available. PMID: 306107 [PubMed - indexed for MEDLINE]
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11. Low DA, Baker JB, Koonce WC, Cunningham DD. released protease-nexin regulates cellular binding, internalization, and degradation of serine proteases. *Proc Natl Acad Sci U S A*. 1981 Apr;78(4):2340-4. PMID: 7017731 [PubMed - indexed for MEDLINE]
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Principal Investigator/Program Director (Last, First, Middle): **PI Name**

Intravenous interleukin-8 inhibits granulocyte emigration from rabbit mesenteric venules without altering L-selectin expression or leukocyte rolling. *J Immunol.* 1993 Dec 1;151(11):6347-57. PMID: 7504019 [PubMed - indexed for MEDLINE]

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C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.